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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/029,876	12/31/2001	Scot Kevin Huber	022650-687	4296

7590 10/03/2003

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EXAMINER

SMALL, ANDREA D SOUZA

ART UNIT	PAPER NUMBER
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1626

DATE MAILED: 10/03/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/029,876	HUBER, SCOT KEVIN	
	Examiner	Art Unit	
	Andrea D Small	1626	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 15 July 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-18 is/are pending in the application.
- 4a) Of the above claim(s) 1-9, 12 and 15-18 and parts of 10-11 and 13-14 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 10,11,13 and 14 is/are rejected.
- 7) ☒ Claim(s) 10-11 and 13-14 is/are objected to.
- 8) ☒ Claim(s) 1-18 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____. |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) <u>12/31</u> . | 6) <input type="checkbox"/> Other: _____. |

DETAILED ACTION

I. Preliminary Matters:

- (a) Applicants response filed 7/16/2003 has been received and entered into the file.
- (b) Applicants claim that this application is a DIV of 09/550,312, now US Patent No. 6,346,542, which claims benefit of 60/129,371 and claims benefit of 60/139,892 is acknowledged.
- (c) The information disclosure statement filed has been received and entered into the file. A signed and initialed copy of the 1449 is attached.

II. Restriction/Election:

- (a) Applicants have elected to prosecute group II, claims 10-14 and have elected a specific organic radical E, which is Mosher's acid. The election was made with traverse. The traversal stated that the restriction requirement is flawed in that it did not establish that a serious burden on the office in examining groups II and III in one application. The examiner respectfully disagrees. There is a serious burden in examining both groups in the same application. Group III involves the further conversion of the products prepared in group II into their acid addition salts. This conversion is patentably distinct from preparing the products of group II. The search for each group is not co-extensive. Searching group II involves searching the end products made therein while searching group III involves searching the acid addition salts of the end products prepared in group II. A separate manual as well as electronic database search would need to be applied to each of the groups. In addition separate searching strategies and evaluations would be required for each of the groups. This plurality of separate searches would impose a serious burden on the office and hence restriction as outline in office action of January 15, 2003 is proper and maintained.

(b) The elected group identified for examination includes the process as claimed in claims 10-14 wherein E is an organic radical which is Mosher's acid.

The claims that read on the above elected group are 10-11 and 13-14 in part. The remaining subject matter of claims 10-11 and 13-14 and claims 1-9, 12 and 15-18 are withdrawn from consideration as being drawn to non-elected inventions. 37 CFR 1.142(b).

III. Rejections:

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

(a) Claims 10-11 and 13-14 rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. Applicants disclosure and claims are lacking in description as neither the disclosure nor the claims describes the essential elements necessary to convey to one of ordinary skill in the art that the Applicant had possession of the invention at the time of the filing of the instant application. These necessary elements include the reaction steps, reaction conditions, such as temperature, pressure, etc., ratios of reactants and products or reagents employed. These essential elements would provide the requisite description necessary for one of ordinary skill in the art to run the process as claimed and obtain the designated enriched enantiomeric product.

(b) Claims 10-11 and 13-14 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter, which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

In *In re Wands*, 8 USPQ2d 1400 (1988), factors to be considered in determining whether a disclosure meets the enablement requirement of 35 U.S.C. § 112, first paragraph, have been described. They are:

1. the nature of the invention:

The nature of the instant invention is a process of preparing products that are enriched in one enantiomer over the other.

2. the state of the prior art:

The state of the prior art is such that there are conventional methodologies for separating out particular enantiomers of compounds, such as HPLC. However, processes that do not involve such conventional methodologies are not well known or well practiced.

3. the predictability or lack thereof in the art:

The predictability of the art is very low when conventional techniques are not used because the (1) reagents that need to be employed to separate out particular enantiomers is not very predictable, some could permanently react with the enantiomer and not result in products that can be easily partitioned from the reagent, (2) reaction conditions that need to be employed are a matter for speculation as certain reaction conditions may be more favorable to the mixture being present, whereas other reaction conditions are more favorable to one enantiomer versus the other, but these reaction conditions depend on the compound under separation.

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4. the amount of direction or guidance present:

The amount of guidance or direction present is little to none. There is no description provided as to the essential steps involved in the process, reaction conditions or even reagents to be employed.

5. the presence or absence of working examples:

There are no examples provided where one of ordinary skill in the art would have some sense of the ranges within which s/he could practice the instantly claimed invention.

6. the breadth of the claims:

The breadth of the claims is vague as the essential elements have not been elucidated upon and theoretically could encompass a plethora of reaction steps, conditions and reagents.

7. the quantity of experimentation needed:

The amount of experimentation required to practice the instantly claimed invention is unduly burdensome. An ordinary skilled artisan would have to evaluate whether the Mosher's acid has to be enantiomerically enriched or whether the starting compound of formula A is enantiomerically enriched so as to correspond to the final product preferred enantiomer? The artisan would have to evaluate what proportions these reactants would be reacted together and under what reaction conditions of temperature, pressure, reagents, etc. The artisan would have to evaluate how the two enantiomers are separated, would it involve filtration, HPLC, decantation, distillation, etc. The artisan would have to evaluate how the reactive groups are removed, would it involve a side reaction, crystallization, evaporation, etc. The artisan would also have to evaluate whether the percentage of enantiomer, finally obtained after all these burdensome evaluations, is in the enriched range.

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8. the level of the skill in the art:

The level of skill in the art, although being high, does not provide the level of predictability needed when employing an unconventional process as is instantly claimed. Therefore, an ordinary skilled artisan would require more guidance than is instantly provided to practice the instant invention without an undue burden.

Thus, the aforementioned claimed subject matter is not enabled.

IV. Objections:


Claims 10-11 and 13-14 are objected to for containing non-elected subject matter. 37 CFR 1.142(b).

V. Contact Information:

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Andrea D. Small whose telephone number is (703) 305-0811.

Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (703) 308-1235.

A facsimile center has been established. The hours of operation are Monday through Friday, 8:30-6:30 PM. The number for accessing the facsimile machine is (703) 746-4984.



Andrea D. Small, Esq.
Patent Examiner
Art Unit 1626, Group 1620
Technology Center 1600

September 29, 2003